

**REMARKS**

Claims 1-47 are pending. Claims 1-28 and 30 are canceled without prejudice. Claims 29-47 are rejected. Claims 29, 31-32 and 34-36 are amended.

Claims 48-67 are new and are supported at least at page 4, line 17 to page 5, line 6; page 6, lines 7-15; page 7, line 14 to page 8, line 3; page 10 Table 1; page 17, line 14 to page 20, line 22, and page 24 Example 2; no new matter has been added.

**CLAIM REJECTIONS UNDER 35 U.S.C. §112**

Claims 29-47 are rejected under 35 U.S.C. §112 ¶1 as not enabled.

Applicants have amended claim 29 to include the chemical compositions disclosed in Table 1 and canceled claim 30 for the anchors. The amendment now limits the structure of A1 and A2; with the teachings of the specification combined with the knowledge of one skilled in the art, applicants respectfully assert that the amount of experimentation for other components is not undue. For example, the specification discloses that binding regions or epitopes 14a, 14b are hydrophilic (page 9, lines 1-8); the determination of such epitopes is not undue, particularly in view of the components provided in Table 1 and the knowledge of one skilled in the art (e.g., saccharides are known binding regions on the surface of red blood cells, etc.). The specification also discloses that lamellar structure 13 may be a micelle, liposome, emulsion, microparticle, microbubble, bounded vesicle, nanoparticle, cell (page 20, line 23 to page 21, line 10); these are known to one skilled the art, thus its determination is not undue, particularly in view of the lamellar structures provided in Table 3. Linkers

are disclosed as flexible compounds that connect a binding epitope to an anchor region (page 8, lines 14-15) with components provided in Table 4. Thus, applicants assert that any experimentation for components with these criteria is within the skill of one in the art and thus is not undue. Accordingly, applicants respectfully request the rejection be withdrawn.

Claims 29-47 are rejected under 35 U.S.C. §112 ¶2 as indefinite.

Applicants believe that the amendment and analysis provided above ascertains the multicomponents systems encompassed by the invention, and thus satisfies the Examiner's request to clarify the claims.

For additional clarification, the specification discloses that effector molecules 30 include fluids for ultrasound, fluorescent compounds for optical imaging, paramagnetic agents for MRI, radionuclides for NMR, and opacification agents for x-ray or CT (page 17, lined 15 to page 18, line 21). One skilled in the art would know the procedure (e.g., ultrasound if a microbubble composition was the effector molecule), and would also know the uses of that procedure to determine if the procedure could be diagnostic, therapeutic, or both. For example, ultrasound may be used for diagnosis (e.g., cardiac imaging) and also for therapy (e.g., sonic therapy (lithotripsy) to break up gallstones). Thus, applicants believe they have complied with the Examiner's request to clarify the claims.

Applicants have amended claims 31-32 and 34-36 as requested by the Examiner solely to advance prosecution; applicants respectfully assert that the claims are clear as filed without amendment.

Applicants respectfully assert that the amended claims assign variables to A1 and A2, and that B1, B2, L1, and L2 variables are determinable without undue experimentation by one skilled in art, for at least the reasons previously analyzed. Thus, applicants believe they have addressed the Examiner's confusion.

Applicants have amended the claims as suggested by the Examiner to clarify identification of method steps.

New claims have been added to protect additional embodiments of the invention.

#### **CLAIM REJECTIONS UNDER 35 U.S.C. §103**

Claims 29, 31, 32, 35, 36, 38-42, and 45-47 are rejected under 35 U.S.C. §103(a) as obvious over Garrity.

Applicants respectfully disagree that Garrity renders applicants method obvious to one skilled in the art. As one example, the Examiner has not indicated where Garrity teaches, suggests, or motivates providing a patient with an assembly where the binding regions relatively self-adjust to form a composition with enhanced binding. As another example, the Examiner has not indicated where Garrity teaches, suggests, or motivates targeting of the composition. As another example, the Examiner has not indicated where Garrity teaches, suggests, or motivates using any lamellar structure other than a liposome. Garrity even indicates this in the title "Liposomal Agents". Such teachings, suggestions, or motivations must come from Garrity as one

component of a *prima facie* case of obviousness; this is lacking. Thus, applicants respectfully request the rejection be withdrawn.

**CONCLUSION**

For the foregoing reasons, applicant's invention is believed to be patentable and an early Notice of Allowance is respectfully requested.

Applicant has submitted a petition for a one-month extension with this Amendment and authorizes the Examiner to charge the fee of \$110, for a one-month extension to Deposit Account No. 23-3000. If any additional fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account No. 23-3000.

The Examiner is invited to contact the applicants' undersigned representative with any questions.

Respectfully submitted,  
WOOD, HERRON & EVANS, L.L.P.

*Beverly A. Lyman*  
Beverly A. Lyman  
Reg. No. 41,961

2700 Carew Tower  
441 Vine Street  
Cincinnati, OH 45202  
(513) 241-2324  
(513) 421-7269 facsimile